REMARKS

Reconsideration and withdrawal of the rejections of this application are respectfully requested in view of the remarks herewith.

Claims 1-35 and 43-46 are pending in the subject application.

No new matter has been added.

I. REJECTION UNDER THE DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 1-18 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-10 of U.S. Patent No. 7,119,061. In addition, claims 20-35 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-22 of U.S. Patent No. 6,900,175 in view of U.S. Patent No. 5,004,605 to Hershenson et al.

Applicant respectfully requests that the rejections be held in abeyance pending the determination of allowable subject matter in this and the cited applications. At that time, if the rejection is still an issue and one or more of the cited applications have issued, Applicant will address the substance of the double patent rejection in an appropriate manner.

II. REJECTION UNDER 35 U.S.C. §103(a)

Claims 1-35 and 43-46 stand rejected as allegedly obvious under 35 U.S.C. § 103 over U.S. Patent No. 5,750,509 to Malabara et al ("Malabara") in view of U.S. Patent No. 5,004,605 to Hershenson et al. ("Hershenson"). The rejection is respectfully traversed.

In order to "establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP §2143.03 citing *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). However, the cited references fail to teach or suggest all of the elements of the present claims. Applicants respectfully submit that the cited references fails to inherently or expressly teach or suggest "dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL." see claim 1.

More specifically, Malabarba does not disclose, teach, or suggest any aqueous pharmaceutical composition containing dlalbavancin, let alone "a pharmaceutically acceptable aqueous composition comprising dalbavancin..., wherein the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL" as recited in the pending claims. Further, this deficiency is not overcome further in view of Hershenson. Accordingly, the cited references do not state a *prima facie* case of obviousness because they do not teach or suggest all of the elements of the rejected claims.

Applicants respectfully submit that the Office has not shown where the motivation to establish a prima facie case of obvious is found in Malabarba. Specifically, the Office has failed to point to any teaching or suggestion in Malabarba to a pharmaceutically acceptable aqueous composition comprising dalbavancin, wherein the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL as claimed in the present

application. The Examiner merely recites bits and pieces from Malabarba using Applicants' disclosure as the blue print to arrive at the claimed invention. This is improper.

For example, the Office assets that Malabarba discloses derivatives of dalbavancin "in the form of liquid solutions (column 27, lines 50-54) at a dosage of form about 30 to about 500 mg per unit (column 28, lines 25-29)", and concludes that "[t]herefore, to formulate antibiotic A 409216 (dalbavancin) in an aqueous composition having the dosage within the range shown by Malabara et al would have been *prima facie* obvious to a person having ordinary skill the art at the time of the claimed invention was made. *Office Action*, at 4-5.

Although the cited passage does literally state "liquid solutions", the passage goes on to provide for many other dosage forms, "Preparations for oral administration may be in the form of capsules, tablets, liquid solutions or suspensions." Malabarba at col. 27, lines 50-51. In addition, the Office asserts that the Malabarba teaches any dosage containing "about 30 to about 500 mg per unit". However, as indicated in Applicants' previous response, Malabarba refers to compositions in only a very general manner and is not concerned with a formulation preparation, let alone a pharmaceutically acceptable aqueous composition comprising dalbavancin, wherein the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL as claimed in the present application.

Again, the Office does not provide any motivation in Malabara to suggest the claimed invention from the bits and pieces from Malabarba. Instead the Office is using Applicants' disclosure as the blue print to arrive at the claimed invention, which is improper.

Further, this deficiency is not overcome further in view of Hershenson. As previously stated, Hershenson relates to low pH pharmaceutical compositions containing "recombinant interferon-B protein (IFN-B) dissolved in an inert carrier medium comprising as a stabilizer/solubilizer in an effective amount either of glycerol or of polyethyleneglycol polymers" (see Abstract of Hershenson). Nowhere does Hershenson disclose, teach or suggest a dalbavancin composition, let alone a composition "wherein the concentration of said dalbavancin said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL" as recited in the pending claims. Thus, the combination of the Malabarba and Hershenson does not disclose, teach or suggest a "a pharmaceutically acceptable aqueous composition comprising dalbavancin wherein the concentration of said dalbavancin in said aqueous composition is from about 0.1 mg/mL to about 100 mg/mL as recited in the pending claims.

Accordingly, the Examiner has not met the standard for an obviousness rejection based upon the well-established rules of law.

Applicants also submit that the Office's reliance on Hershenson for the use of "dextrose as a stabilizing agent" or any other stabilizing agent is misplaced. As mentioned in Applicants' previous response Hershenson teaches the use of "solubilizers/stabilizers" to maintain a "stable aqueous solution." In contrast, Malabarba contemplates suspending, stabilizing and/or dispersing agents to provide uniformity of a dispersed phase. Therefore, one of skill in the art

would not look to modify the compositions disclosed in Malabarba to include a solubilizer/stabilizer as described in Hershenson.

Therefore, Applicants respectfully submit the claims are not rendered obvious over the cited references and respectfully request that the § 103 rejections be withdrawn

CONCLUSION

In view of the remarks, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

Date: October 15, 2008

/Christian Smolizza/
Christian M. Smolizza
Attorney for Applicant
Reg. No. **46,319**

Pfizer Inc
Patent Dept., 150-5-49
235 East 42nd Street
New York, NY 10017-5755
(212) 733-**9094**